

Progress Report on COSMOS pre-test
Mireille Toledano and Paul Elliott
Imperial College London
November 2009

Invitations: Between late May and mid June 2009, invitation packs and consent forms were sent out to 4,500 mobile phone customers supplied by 3 mobile operator companies (Orange, O2 and Vodafone). 4325 reminder letters were sent out in early July 2009.

Consents: To date, 230 completed consent forms have been returned, giving a consent response rate of 5.1%. For all these people, we therefore have permission to access long term NHS health records and mobile phone traffic data from operators. This 5% response rate is comparable to current response rates in the UK Biobank study (5-8%).

Questionnaire responses: From the 230 people who gave consent, 175 questionnaires were filled in and submitted online/returned by post.

Participants had the option of registering and filling in the questionnaire online, or requesting a paper questionnaire, which they then filled in and returned by post. 87 (37.8%) of people giving consent requested a paper questionnaire, of whom 55 (63.2%) filled it in and returned it. Of the 143 people giving consent who did not request a paper questionnaire, 120 (83.9%) registered and filled in the questionnaire online.

We found that some people sent the consent form but then failed to complete the questionnaire either online or on paper, and some registered/completed online, but did not return their consent form. For these people, where possible, we contacted them by phone and/or e-mail to encourage them to provide the missing information.

To date, there remain 14 people who registered and filled in the questionnaire online, but who have not returned their consent forms. By registering and completing online they have clearly indicated their willingness to take part, and perhaps think that by doing so they have implicitly given their consent. By introducing the option of e-consent for all online participants to the main launch we would boost the number of individuals with full consent in the study and avoid loss of valuable data from willing participants.

Online vs Paper responses: Of the 175 completed questionnaires, 120 (68.6%) were completed online, and 55 (31.4%) completed on paper.

As a result we have considered an 'online-only' approach for the main launch of the study. To assess the impact of removing the paper questionnaire option from the main launch, we surveyed a proportion of those who requested paper questionnaires about their willingness to complete the study online, if there was no paper option. Of those surveyed, 79% stated that they would complete the questionnaire online. When the responses of those surveyed are split according to whether they requested the paper questionnaire or actually completed and returned it in the pre-test, 71% of the former stated willingness to complete online and 85% of the latter stated willingness to complete online.

Based on this survey, and the pre-test results, we calculate that if the pre-test had mailed out an invitation with consent form but had only offered participants an online-

questionnaire option, we would have 'lost out' on 8 of the 175 completed questionnaires.

Completion of consents and questionnaires

Consent forms were fully completed, with the exception of 2 which were filled in but unsigned (we are following this up in order to gain signatures). As a result we currently have consent to access long term health records and mobile traffic data for 228 people. 231 traffic data requests have been made to operators so far (relating to 226 participants – some with multiple mobile phones). Of these 231 requests, 200 have been matched to traffic data by the operators, and 31 are still to be run through the matching process for a second time to check for churners and porters.

Sample stratification: In the pre-test, we oversampled for males (60% male, 40% female) on the assumption that response rate from males would be lower. However, response by sex reflected this stratification. Therefore, for the main launch, we will revert to approaching equal proportions of men and women.

The main launch – achieving the target number in the cohort, and projected power:

In order to achieve the target number of 90-100,000 in the cohort, and thus the projected power, we need to scale up the numbers in the initial mail-out. This has potential cost implications but by redesigning the invitation process we will be able to contain costs within the original budget.

We have considered the various possibilities, based on the pre-test results, to achieve the required sample size within cost constraints and discussed these with operators. In our view, the most efficient and cost effective approach is to mail people an invitation pack including consent form but offer an online questionnaire only, incorporating the option of e-consent. A small proportion of people who opted for the paper version of the questionnaire would be lost since not all have access to internet, but savings in terms of questionnaire printing, mailing and scanning would be considerable, which would allow for a larger initial mail-out.

We have calculated corrected response rates to reflect using an online-only questionnaire. These remain conservative estimates, because they do not take into account the potential positive effect of the media release which will accompany the main launch. Based on the survey feedback mentioned earlier, we have calculated a consent response rate of 4.7%, on the assumption that all those who requested a paper questionnaire, but later stated that they would be willing to complete the questionnaire online, would in fact do so. Under this scenario, to achieve a cohort of 90-100,000, we would need to mail out invitations to ~2.13 million people. If we also assume that e-consent is introduced (subject to ethical approval), this would increase the corrected consent response rate to 5.0% (as we can include those who completed the questionnaire online, but failed to return their paper consent form in the pre-test), and the initial mail-out required to achieve a 90-100,000 UK cohort would decrease to 2.0 million. Operators have already agreed to scale up the number of customers they are willing to provide for the initial invitation mailing (up to 600,000 customers per each of the 4 operators i.e. a maximum total of 2.4 million).

Summary

By making the proposed adjustments outlined above to the study design and by putting out the services required to competitive tender we are confident that we can achieve a UK cohort of 90-100,000, as planned, and within budget. The main launch will be accompanied by a communications strategy which will raise public awareness of this study and therefore help to boost response rates.